DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for revised labeling for the use of single-ingredient monensin Type A medicated articles to make Type C medicated feeds used for the prevention and control of coccidiosis in feedlot cattle. The regulations are being amended to remove a redundant entry for use of monensin in Type C medicated cattle feeds.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578, e-mail: *jmessenh@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 95–735 for use of RUMENSIN 80 (monensin sodium) Type A medicated article. The supplemental NADA provides revised labeling for Type C medicated feeds containing 10 to 30 grams per ton (g/ton) of monensin used for the prevention and control of coccidiosis caused by *Eimeria bovis* and *E.*

zuernii in feedlot cattle. This revised labeling replaces labeling approved in 1998 for this indication (64 FR 5158, February 3, 1999). The supplemental application is approved as of December 12, 2003, and the regulations are amended in 21 CFR 558.355(f)(3)(vii) to remove indications for improved feed efficiency in cattle feeds containing 10 to 30 g/ton of monensin. This indication for use is already codified in 21 CFR 558.355(f)(3)(i) for cattle feeds containing 5 to 30 g of monensin per ton.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.355 [Amended]

■ 2. Section 558.355 *Monensin* is revised in paragraph (f)(3)(vii)(*a*) by removing ''improved feed efficiency; for''; and in paragraph (f)(3)(vii)(*b*) by removing ''feed continuously to provide 50 to 360 milligrams monensin per head per day. For prevention and control of coccidiosis,''.

Dated: January 30, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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